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10/540,829	02/21/2006	Ganugapati Vijaya Bhaskar	DAIRY88.011APC	2247
20995	7590	05/14/2010		
KNOBBE MARLENS OLSON & BEAR LLP			EXAMINER	
2040 MAIN STREET			BADR, HAMID R	
FOURTEENTH FLOOR			ART UNIT	PAPER NUMBER
IRVINE, CA 92614			1781	
			NOTIFICATION DATE	DELIVERY MODE
			05/14/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/540,829	<b>Applicant(s)</b> BHASKAR ET AL.
	<b>Examiner</b> HAMID R. BADR	<b>Art Unit</b> 1781

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on **RCE, 02 February 2010**.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) **1-19 and 21-26** is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) **1-19 and 21-26** is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/06)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

**DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/02/2010 has been entered.

1. Claims 1-19 and 21-26 are being considered on the merits.

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 1-10, 12, and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claims 1-10 are indefinite for reciting in claim 1 "substantially" nugget free. It is unclear what is meant by "substantially". "Substantially" is not defined by the claims nor is it explained in the specification. It is not clear what the applicants regard as the invention. As set forth in MPEP 2173.05(b), in *In re Mattison*, 509 F.2d 562, 184 USPQ 484 (CCPA 1975), the court held that the use of "substantially" was definite in view of the general guidelines contained in the specification. However, there are no such general guidelines set forth in the present specification.

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4. Claim 12 is indefinite for "enhanced solubility". The term "enhanced" is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear over what standard the solubility is to be "enhanced".

5. Claim 14 is indefinite for "wherein the high denatured whey protein content is a content such that the whey protein content of curd produced". It is not clear what is meant by this phrase.

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Delespaul et al. (FR 2 452 879; Official Translation; hereinafter R1).

3. R1 discloses a process for making cheese. It specifically discloses a process for preparing milk products with improved texture. In classical cheese making, a coagulation stage is used where the milk is coagulated using an acid or pressure or notably microbial enzymes. (page 2, first paragraph).

4. R1 discloses that a more recent technique is the cheese making process by ultrafiltration consisting of concentrating milk proteins using membranes. (page 2, paragraph 3).

5. R1 discloses that the proteinaceous concentrate is coagulated by adding enzymes (rennet) and can be acidified by chemical acidification or bacteriological acidification (bacterial lactic fermentation) and by pressure to obtain cheese. The obtained cheese can undergo classical operations of acidification and aging. (page 2, last paragraph).

6. R1 teaches of heating the milk before the ultrafiltration process or heating the retentate of the ultrafiltration process to temperatures which can reach sterilization. This thermal treatment is effectuated at 75-150C and allows obtaining cheeses having fine and homogenous texture. R1 further explains that one can attribute the favorable effect of the heat treatment to partial denaturation of proteins or modification of the physical state of calcium present. (page 2, line 37- page 3, line7). The heat treatment should not be extensive, because due to extensive heat treatment, the viscosity of the product will be modified . (page 4, first paragraph).

7. R1 teaches the decalcification of milk by ion exchange using cationic resins. Such resins can be charged for example by sodium, potassium, ammonium or hydrogen ion or by divalent ions such as magnesium, zinc, copper or trivalent ions depending on the salt concentration, pH and the desired composition of the material. (page 5, 3<sup>rd</sup> paragraph)

8. R1 discloses that the decalcification can be 0-80% and preferably 20-40% (page 4, line20-21). The decalcification extent will depend on the type of cheese desired (page 5, last paragraph).

9. R1 discloses that the decalcification is optionally associated with a heat treatment between 75-150C and preferably 90-110C. R1 restates that the decalcification together with heat treatment will allow obtaining a fine and homogenous texture of cheese. (page 7, 3<sup>rd</sup> paragraph).

10. R1 discloses that the calcium can be reintroduced by adding a calcium salt or by mixing at least one non-decalcified product such as milk. (page 7, 4<sup>th</sup> paragraph).

11. R1 gives examples of making cheese using calcium depleted milk and rennet. Decalcification is carried out to 30% in Example 1 and to 100% in Example 2. In Example 3, heat treatment is carried out by injection of vapor at 120C. (pages 8-9). The cheese is subjected to further processing (Examples).

12. While R1 does not explicitly disclose a pH range at which whey proteins are heat denatured, the pH range as presently claimed is inherent to milk. R1 also discloses the heating process and attributes the favorable effect of the thermal process treatment to a partial denaturation of proteins. (page 4, lines 6-7). Therefore the limitation of heating the milk at pH 6.0-7.0 is anticipated by R1. Denaturation of whey proteins at high temperature and longer duration is known in the art and is practiced routinely.

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 1-9, 11-19 and 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhaskar et al. (WO 01/41578; hereinafter R2) in view of Delespaul et al. (FR 2 452 879; Official Translation; hereinafter R1).
15. R2 discloses the production of dried milk protein concentrates (MPC) which have been calcium depleted to an extent which allows improvements in the use of dried milk protein concentrates in cheese manufacture. The invention includes a method of cheese manufacture comprising a) dispersing in milk a dried MPC or MPI having at least 70% dry matter as milk proteins, b) treating the mixture with a coagulating enzyme to produce a curd, c) processing the curd to make cheese; Wherein the incorporation of calcium depleted MPC allows the manufacture of substantially nugget-free cheese.  
(Abstract).
16. R2 discloses the steps of incorporation of a dried MPC into milk and the subsequent cheese making process. (page 2, lines 8-15).
17. R2 discloses the extent of decalcification required as 20-100% depending on the milk protein content of the MPC. (page 2, lines 17-22)
18. R2 discloses the use of ion exchange, acidification and addition of chelating agents for the decalcification process. (page 3, lines 4-10).
19. R2 discloses the drying process which can be done by standard drying processes. Drying may be preceded by dewatering. (page 4, lines 31-34)

20. R2 gives Examples of preparation of dried calcium depleted MPC (page 7) , the solubility of the dried product in water (page 9, Example 2), and processes for cheese preparation (page 9, Example 3).
21. R2 basically disclose most aspects of the presently claimed invention, however, R2 is silent regarding the heat treatment of the raw material for decalcification.
22. R1 discloses that the decalcification is optionally associated with a heat treatment between 75-150C and preferably 90-110C. R1 restates that the decalcification together with heat treatment will allow obtaining a fine and homogenous texture of cheese. (page 7, 3<sup>rd</sup> paragraph).
23. R1 teaches of heating the milk before the ultrafiltration process or heating the retentate of the ultrafiltration process to temperatures which can reach sterilization. This thermal treatment is effectuated at 75-150C and allows obtaining cheeses having fine and homogenous texture. R1 further explains that one can attribute the favorable effect of the heat treatment to partial denaturation of proteins or modification of the physical state of calcium present. (page 2, line 37- page 3, line7). The heat treatment should not be extensive, because due to extensive heat treatment, the viscosity of the product will be modified . (page 4, first paragraph).
24. While R1 discloses the temperature range at which the heat treatment can be carried out, and it specifically points out to the point that extensive denaturation will affect the viscosity of the product, it does not mention duration of time during heat treatment. However, knowing the temperature in the range as taught by R1, those of skill in the art can optimize the time required for heat treatment as presently claimed.

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25. Given that R1 discloses the heating of the raw material to denature the whey proteins, the treatment methods of claim 19 are obvious and conventional methods in the art.

26. It would be also obvious to perform the heat treatment using indirect heat heating as presently claimed. An example of indirect heating is a plate heat exchanger which is well known in the art.

27. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to follow the teachings of R2 and R1 to prepare high yield MPC and MPI of the presently claimed invention and to make cheese free of nuggets which results in more consistent and efficient cheese making (page 1, lines 21-23, R2). Absent any evidence to contrary and based on the combined teachings of the cited references, there would be a reasonable expectation of success in preparing calcium depleted milk concentrates and manufacturing cheese using the same.

#### ***Response to Arguments***

Applicants arguments have been thoroughly reviewed. These arguments are not persuasive for the following reasons.

1. Applicants argue that the Examiner objected to the use of "substantially nugget-free" in claim1 while "substantially nugget free" is understood by an artisan.
  - a. While Applicants argue that "substantially" has a well understood meaning, it is the examiner's position that the scope of the claims would not be understood by one skilled in the art and that there is no evidence that one of ordinary skill in the art would

understand what is meant by cheese that is "substantially" nugget-free or what amount of nugget can be present, i.e. 0.01%, 0.1%, 5%, etc, and the cheese still considered to be substantially nugget-free.

2. Applicants argue that the heat treatment of R1 is applied as a part of a cheese making process with the MPC making process of R2.

a. The heat treatment of the raw material as disclosed by R1 is done to denature the whey proteins. This will cause the incorporation of whey proteins in the cheese with a higher yield. It further affects the cheese texture. Since both R1 and R2 are concerned with the production of calcium depleted milk concentrates, the teachings of R1, regarding the heat treatment, is well fitted to be used with the teachings of R2.

However, note that while R1 does not disclose all the features of the present claimed invention, R1 is used as teaching reference, and therefore, it is not necessary for this secondary reference to contain all the features of the presently claimed invention, *In re Nievelt*, 482 F.2d 965, 179 USPQ 224, 226 (CCPA 1973), *In re Keller* 624 F.2d 413, 208 USPQ 871, 881 (CCPA 1981). Rather this reference teaches a certain concept, and in combination with the primary reference, discloses the presently claimed invention.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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